



8377 '02 APR 12 P1:35

MAR 29 2002

Ms. Janet Sperry  
Marketing Assistant  
Flora, Inc.  
P.O. Box 73  
Lynden, Washington 98264

Dear Ms. Sperry:

This is in response to your letter of February 12, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Flora, Inc. is making the following claim for the product **Super 5 Acidophilus**, which you believe is a product that is a dietary supplement.

This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, cannot be marketed as a dietary supplement. Among other claims for the product, the notification states that the product "helps maintain desirable micro-organisms in the mouth, teeth, gums, and throat." This claim is a claim that describes an effect of the product that is achieved prior to its ingestion. Therefore, the product does not meet all of the elements of the statutory definition of a dietary supplement, namely that it be a product intended for ingestion, when labeled for use to maintain desirable micro-organisms in the mouth, teeth, gums, and throat and it is, therefore, not a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

This product is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended

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for ingestion.” The term “ingestion” has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff’d, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term “ingestion” means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman’s Medical Dictionary (4th Lawyer’s Ed. 1976) (defining ingestion as the “introduction of food and drink into the stomach.”); Webster’s Third New International Dictionary (1976) (defining ingestion as “the taking of material (as food) into the digestive system.”)....

The interpretation of the term “ingestion” to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, a product that is used to “...maintain desirable micro-organisms in the mouth, teeth, gums, and throat” is not subject to regulation as a dietary supplement because it is not “intended for ingestion” because it is intended, in part, to exert its effect on the structure or function of the body prior to being ingested.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

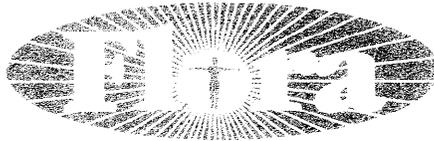
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FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

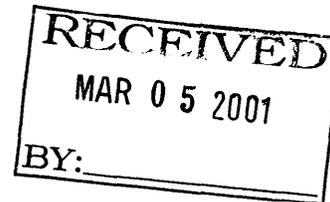
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



Quality Health From God's Pharmacy

February 12, 2002



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

Re: Structure/Function Label Claim

This letter is to notify the Food and Drug Administration that within the past 30 days our company has begun to market **Super 5 Acidophilus<sup>+</sup>** Dietary Supplement, with the following statement of nutritional support included on the label and in labeling for the product:

Each tablet of Udo's Choice Super 5 Acidophilus<sup>+</sup> contains not less than 1 billion viable cells to help support the entire digestive tract. Especially helpful in supporting normal, healthy microflora of the small and large intestine. Super 5 also helps maintain desirable micro-organisms in the mouth, teeth, gums, and throat.

The dietary ingredients of the product that are the subject of the above statements are **Lactobacillus Acidophilus, Bifidobacterium bifidus, Streptococcus thermophilus, Lactobacillus salivarius, Lactobacillus bulgaricus.**

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement(s) is truthful and not misleading.

Very truly yours,

Flora Inc.

Janet Sperry  
Marketing Assistant  
Labels & Packaging

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Flora, Inc. P.O. Box 73, Lynden, WA 98264 (360) 354-2110 (800) 498-3610 FAX (360) 354-5355  
Eastern Branch: 62 Seaview Blvd., Port Washington, NY 11050

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